K132352

510(k) SUMMARY
SAS™ Influenza A Test K041441

This 510(k) summary of safety and effectiveness submission is in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted by:	SA Scientific, Ltd. 4919 Golden Quail San Antonio, TX 78240 210-699-8800
Establishment Reg. No:	1645225
Contact Person:	Nelson Torres
Date Prepared:	July 22, 2013
Proprietary Name:	SAS™ Influenza A Test
Classification Name:	Antigens, CF (including CF control), Influenza virus A, B, C
Device Classification:	21 CFR Part 866.3330
Regulatory Class:	Class I
Classification Advisory Committee:	Microbiology
Product Code:	GNX
Substantial Equivalence:	SAS™ Influenza A Test, manufactured by SA Scientific, Ltd., San Antonio, TX.
Device Description:	The SAS™ Influenza A Test utilizes antibodies against influenza type A viral nucleoproteins. The SAS™ Influenza A test begins with an extraction of Type A nucleoproteins. After the extraction has been completed, the sample is placed into the sample well of the test. The specimen is absorbed and migrates via capillary action through membranes that contain dried gold conjugated antibody, which is specific for influenza A viral nucleoproteins. If these nucleoproteins are present, a "half-sandwich" immunocomplex is formed. The membrane contains immobilized antibody to influenza A nucleoproteins, which binds the "half sandwich" complex. Thus, in the presence of influenza A nucleoproteins, a "whole sandwich" immunocomplex is formed and a visible, pink-colored line develops in the specimen zone of the test device. In the absence of an influenza A antigen, a "sandwich" immunocomplex is not formed and a negative result is indicated. To serve as a procedural control, a pink-colored control line will always appear in the control zone of each strip regardless of the presence or absence of influenza A nucleoproteins.
Intended Use:	SAS™ Influenza A Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of influenza A viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of Influenza Type B viral antigen or Influenza Type C viral antigen. This test is for professional use only.

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Negative results do not preclude infection with influenza A and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.

Conditions for Use: For prescription use only.

Quality Controls: The SAS™ Influenza A Test provides an internal procedural quality control. It is recommended that external quality controls be assayed following the user's laboratory's standard quality control procedures and in conformance with local, state and federal regulations or accreditation organizations as applicable

Device comparison: The SAS™ Influenza A is a rapid immunoassays utilizing immunochromatographic technology for the visualization of influenza A antigen. Each utilizes an antibody conjugated to colored particles and an antibody printed onto a membrane. The chemistry of the predicate device and the proposed device is identical; the only difference is that the new inserts include sensitivity data for H7N9.

Performance Summary: This test has been shown to detect the Influenza A/Anhui/1/2013 (H7N9) virus cultured from a positive human specimen however, the performance characteristics of this test with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The SAS FluAlert A Test can detect influenza A virus, but cannot differentiate influenza subtypes.

Clinical Summary: Please see K041441 for Clinical Summary

Note: Performance characteristics for detecting the 2013 H7N9 influenza virus from human specimens have not been established

Analytical Sensitivity
(Limit of Detection): The analytical sensitivity of the SAS™ *FluAlert* A Test was determined for 2013 H7N9 using strain A/Anhui/1/2013. Each strain was serially diluted in SAS™ Influennza A extraction buffer. Results for A/Anhui/1/2013 are included in the summary table below.

Influenza Viral Strain	**ATCC**	**LoD** $TCID_{50}$/0.2 ml
H1N1 A/PR/3/34	VR-95	1.2×10^5
H3N2 A/Aichi/2/68	VR-547	5.6×10^2
H3N2 A/Hong Kong/8/6/8	VR-544	3.5×10^3
H1N1 A/FM/147	VR-97	7.9×10^3
H3N2 A/Victoria/3/75	VR-822	4.5×10^5
H1N1 A/California/04/09	NR-13658	1.4×10^3
H7N9 A/Anhui/1/2013	CDC ID 2013759189	1.0×10^8 EID_{50}/mL

*This test has been shown to detect the Influenza A/Anhui/1/2013 (H7N9) virus cultured from a positive human specimen however, the performance characteristics of this test with clinical specimens that are positive for the 2013 H7N9 influenza virus have not been established. The SAS Influenza A Test can detect influenza A viruses, but cannot differentiate influenza subtypes.
**This viral strain was obtained from the CDC with a known titer. SA Scientific, Ltd did not verify this titer.

Conclusion:	The information presented in the premarket notification demonstrates that the SAS™ Influenza A Test reacts with a cultured strain of 2013 H7N9 (Influenza A/Anhui/1/2013). Although this test has been shown to detect the 2013 H7N9 from a cultured isolate, the performance characteristics of this test with clinical specimens that are positive for the 2013 H7N9 influenza virus have not been established. The SAS Influenza A Test can detect influenza A viruses, but cannot differentiate influenza subtypes. This viral strain used in this study was obtained from the CDC with a known titer. SA Scientific, Ltd did not verify this titer.

510(k) SUMMARY
SAS™ FluAlert A & B Test K080380

This 510(k) summary of safety and effectiveness submission is in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted by:	SA Scientific, Ltd. 4919 Golden Quail San Antonio, TX 78240 210-699-8800
Establishment Reg. No:	1645225
Contact Person:	Nelson Torres
Date Prepared:	July 22, 2013
Proprietary Name:	SAS™ FluAlert A & B Test
Classification Name:	Antigens, CF (including CF control), Influenza virus A, B, C
Device Classification:	21 CFR Part 866.3330
Regulatory Class:	Class I
Classification Advisory Committee:	Microbiology
Product Code:	GNX
Substantial Equivalence:	Substantially equivalent to the SAS™ FluAlert A&B Test, manufactured by SA Scientific, Ltd., San Antonio, TX.
Device Description:	The SAS™ FluAlert A & B Test utilizes antibodies against influenza type A and influenza type B viral nucleoproteins. After the extraction has been completed, the sample is placed into two separate sample wells. The specimen is absorbed and migrates via capillary action through membranes that contain dried gold conjugated antibody, which is specific for either influenza A or influenza B viral nucleoproteins. If these nucleoproteins are present, a "half-sandwich" immunocomplex is formed. The membrane contains immobilized antibody to influenza A or influenza B nucleoproteins, respectively, which bind the "half sandwich" complex. Thus, in the presence of influenza nucleoproteins, a "whole sandwich" immunocomplex is formed and a visible, pink-colored line develops in the specimen zone of the test device. In the absence of an influenza antigen, a "sandwich" immunocomplex is not formed and a negative result is indicated. To serve as a procedural control, a pink-colored control line will always appear in the control zone of each strip regardless of the presence or absence of influenza A or influenza B nucleoproteins.
Intended Use:	SAS™ FluAlert A & B Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of Influenza A and Influenza B viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of Influenza Type C viral antigen. This test is for professional use only.

Negative results do not preclude infection with influenza A and/or influenza B and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.

Conditions for Use: For prescription use only.

Quality Controls: The SAS™ Influenza A & Influenza B Test provides two (2) internal procedural quality controls. It is recommended that external quality controls be assayed following the user's laboratory's standard quality control procedures and in conformance with local, state and federal regulations or accreditation organizations as applicable

Device comparison: The SAS™ FluAlert A&B Test is a rapid immunoassay tests utilizing immunochromatographic technology for the visualization of Influenza A & Influenza B viral nucleoprotein antigens. Each utilizes an antibody conjugated to colored particles and an antibody printed onto a membrane. The chemistry of the predicate devices and the proposed device is identical; the only difference is that the new inserts include sensitivity data for H7N9.

Performance Summary: This test has been shown to detect the Influenza A/Anhui/1/2013 (H7N9) virus cultured from a positive human specimen. However, the performance characteristics of this test with clinical specimens that are positive for the 2013 H7N9 influenza virus have not been established. The SAS FluAlert A&B Test can distinguish between influenza A and B viruses, but cannot differentiate influenza subtypes.

Clinical Summary: Please see K080380 for Clinical Summary

Note: Performance characteristics for detecting the 2013 H7N9 influenza virus from human specimens have not been established

Analytical Sensitivity (Limit of Detection): The analytical sensitivity for the SAS™ FluAlert A&B Test was determined for 2013 H7N9 using strain A/Anhui/1/2013. The strain was received from the CDC with a known EID_{50} concentration but was not verified by SA Scientific. The strain was serially diluted in SAS™ FluAlert extraction buffer and assayed using the SAS™ FluAlert A&B Test. Results for A/Anhui/1/2013 are included in the summary table below.

Influenza Viral Strain	**ATCC**	**LoD** $TCID_{50}$/0.2 ml
H1N1 A/PR/3/34	VR-95	1.2×10^5
H3N2 A/Aichi/2/68	VR-547	5.6×10^2
H3N2 A/Hong Kong/8/6/8	VR-544	3.5×10^3
H1N1 A/FM/147	VR-97	7.9×10^3
H3N2 A/Victoria/3/75	VR-822	4.5×10^5
H1N1 A/California/04/09	NR-13658	1.4×10^3
*H7N9 A/Anhui/1/2013	CDC ID 2013759189	**1.0×10^8 EID_{50}/mL
Influenza B B/Lee/40	VR-101	9.9×10^4

Influenza B B/Allen/45	VR-102	5.6×10^2
Influenza B B/Mass/3/66	VR-523	4.5×10^2
Influenza B B/Taiwan/2/62	VR-295	3.5×10^1
Influenza B B/Maryland/1/59	VR-296	1.6×10^2

*This test has been shown to detect the Influenza A/Anhui/1/2013 (H7N9) virus cultured from a positive human specimen however, the performance characteristics of this test with clinical specimens that are positive for the 2013 H7N9 influenza virus have not been established. The SAS FluAlert A&B Test can distinguish between influenza A and B viruses, but cannot differentiate influenza subtypes.
**This viral strain was obtained from the CDC with a known titer. SA Scientific, Ltd did not verify this titer.

Cross Reactivity Study: The cross-reactivity for the SAS™ FluAlert A&B Test was determined for 2013 H7N9 using strain A/Anhui/1/2013. The cultured viral strain was tested on the SAS™ FluAlert A&B Test at the indicated concentrations. The cross-reactivity of A/Anhui/1/2013 in the "B" potion of the SAS™ FluAlert A&B Test was added to the summary table below.

Virus	ATTC/Lot #	Concentration	"A" portion of the SAS™ FluAlert A&B	"B" portion of the SAS™ FluAlert A&B
Adenovirus 5	10-198-000	1.2×10^{10}	Neg	Neg
Adenovirus 7	VR7	3.2×10^3 $TCID_{50}$ /0.2 ml	Neg	Neg
Adenovirus 10	VR1087	3.2×10^3 $TCID_{50}$ /0.2 ml	Neg	Neg
CoxsackieA9	VR186	3.2×10^2 $TCID_{50}$ /0.2 ml	Neg	Neg
CoxsackieB5	VR185	3.2×10^6 $TCID_{50}$ /0.2 ml	Neg	Neg
Cytomegalovirus	021301	20 µg/ml	Neg	Neg
Echovirus11	VR1052	NA	Neg	Neg
Echovirus3	VR1040	1×10^4 $TCID_{50}$ /0.2 ml	Neg	Neg
Echovirus 6	VR1044	3.2×10^6 $TCID_{50}$ /0.2 ml	Neg	Neg
HSV-1	2J30000	15 µg/ml	Neg	Neg
HSV-2	8J29502	15 µg/ml	Neg	Neg
Varicella zoster	1102097	12 µg/ml	Neg	Neg
Parainfluenza 1	VR907	5.6×10^6 $TCID_{50}$ /0.2 ml	Neg	Neg
Parainfluenza 2	VR92	1.8×10^5 $TCID_{50}$ /0.2 ml	Neg	Neg
Parainfluenza 3	VR93	3.2×10^6 $TCID_{50}$ /0.2 ml	Neg	Neg
RSV Long	VR26	$0.1 \times 10^{5.5}$ $TCID_{50}$ /0.2 ml	Neg	Neg
RSV B	VR1400	$0.1 \times 10^{5.25}$ $TCID_{50}$ /0.2 ml	Neg	Neg
Influenza B Allen	VR102	3.2×10^3 $TCID_{50}$ /0.2 ml	Neg	
Influenza B Lee	VR101	3.2×10^6 $TCID_{50}$ /0.2 ml	Neg	
Influenza B Mass	VR523	1.8×10^3 $TCID_{50}$ /0.2 ml	Neg	
Influenza B Maryland	VR296	1×10^4 $TCID_{50}$ /0.2 ml	Neg	
Influenza B Taiwan	VR295	5.6×10^2 $TCID_{50}$ /0.2 ml	Neg	
Influenza A (H1N1) PR	VR95	1.8×10^4 $TCID_{50}$ /0.2 ml		Neg

Influenza A (H3N2) Aichci	VR547	1.8 x 10^6 $TCID_{50}$ /0.2 ml		Neg
Influenza A (H3N2) Hong Kong	VR544	5.6 x 10^4 $TCID_{50}$ /0.2 ml		Neg
Influenza A FM	VR97	3.2 x 10^4 $TCID_{50}$ /0.2 ml		Neg
Influenza A (H3N2) Victoria	VR822	1.8 x 10^6 $TCID_{50}$ /0.2 ml		Neg
Influenza A (H1N1) California/04/09	NR-13658	1.1 x 10^4 $TCID_{50}$ /0.2 ml		Neg
Influenza A (H7N9) Anhui/1/2013	CDC ID 2013759189	1.0 X 10^9 EID_{50}/ ml		Neg

*This test has been shown to detect the Influenza A/Anhui/1/2013 (H7N9) virus cultured from a positive human specimen however, the performance characteristics of this test with clinical specimens that are positive for the 2013 H7N9 influenza virus have not been established. The SAS FluAlert A&B Test can distinguish between influenza A and B viruses, but cannot differentiate influenza subtypes.

**This viral strain was obtained from the CDC with a known titer. SA Scientific, Ltd did not verify this titer.

Conclusion:

The information presented in the premarket notification demonstrates that the SAS™ FluAlert A&B Test reacts with a cultured strain of 2013 H7N9 (FluA/Anhui/1/2013). There is no cross-reactivity observed on the "B" portion of the SAS™ FluAlert A&B Test. Although this test has been shown to detect the 2013 H7N9 from a cultured isolate, the performance characteristics of this test with clinical specimens that are positive for the 2013 H7N9 influenza virus have not been established. The SAS FluAlert A&B Test can distinguish between influenza A and B viruses, but cannot differentiate influenza subtypes. This viral strain used in this study was obtained from the CDC with a known titer. SA Scientific, Ltd did not verify this titer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NELSON TORRES
QA/RA SPECIALIST
SA SCIENTIFIC
4919 GOLDEN QUAIL
SAN ANTONIO TX 78240

August 22, 2013

Re: K132352
Trade/Device Names: SAS™ Influenza A and SAS™ FluAlert A & B Tests
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: I
Product Code: GNX
Dated: July 22, 2013
Received: August 2, 2013

Dear Mr. Torres:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your devices on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number: K132352

Device Name: SAS™ FluAlert A & B Test

Indications for Use:

SAS™ FluAlert A & B Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of Influenza A and Influenza B viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of Influenza Type C viral antigen. This test is for professional use only.

Negative results do not preclude infection with influenza A and/or influenza B and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH)

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Indications for Use Form

510(k) Number: K132352

Device Name: SAS™ Influenza A Test

Indications for Use:

SAS™ Influenza A Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of influenza A viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of Influenza Type B viral antigen or Influenza Type C viral antigen. This test is for professional use only.

Negative results do not preclude infection with influenza A and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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